REMARKS

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Claims 5-7, 11-16, 29, 33-37, 39, 45 and 49 are pending herein. Claims 5, 33 and 45 are amended to recite that X^1 is a reactive group for biopolymer synthesis from monomers to produce biopolymers selected from among polypeptides, oliogonucleotides, oligosaccharides and peptide nucleic acid (PNA). No new matter has been added.

Attached to this response are references relied upon in the arguments below to demonstrate the "reactive group" and "reactive group that effects biopolymer synthesis" are terms understood by those of skill in the art.

THE REJECTION OF CLAIMS 5, 33 AND 45 UNDER 35 U.S.C. §112, SECOND PARAGRAPH

Claims 5, 33 and 45 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite in the recitation of "any reactive group that effects biosynthesis of biopolymers" because it is alleged that this term, which is "relative," is not defined by the claim, and because the claims do not recite groups that effect biosynthesis of biopolymers. Reconsideration of the grounds for this rejection is respectfully requested in view of the amendments herein and the following remarks.

Relevant law

Claims are not read in a vacuum but instead are considered in light of the specification and the general understanding of the skilled artisan. Rosemount Inc. v. Beckman Instruments, Inc., 727 F.2d 1540, 1547, 221 USPQ 1, 7 (Fed. Cir. 1984), Caterpillar Tractor Co. v. Berco, S.P.A., 714 F.2d 1110, 1116, 219 USPQ 185, 188 (Fed. Cir. 1983). When one skilled in the art would understand all of the language in the claims when read in light of the specification, a claim is not indefinite.

35 U.S.C. §112, second paragraph requires only reasonable precision in delineating the bounds of the claims. The claim language is satisfactory if it *reasonably apprises* those of skill in the art of the bounds of the claimed invention and is as precise as the subject matter permits. Shatterproof Glass Corp.v. Libby-Owens Ford Col, 758 F.2d 613, 624, 225 USPQ 634, 641 (Fed. Cir), cert dismissed, 106 S. Ct. 340 (1985).

If the claims, read in light of the specification, reasonably apprise those skilled in the art of the utilization and scope of the invention, and if the language is as precise as the subject matter permits, the courts can demand no more:

> [i]t is not necessary that a claim recite each and every element needed for the practical utilization of the claimed subject matter (Bendix Corp. v United States, 600 F.2d 1364, 1369, 220 Ct. Cl. 507,514, 204 USPQ 617, 621 (1979); See, also, Carl Zeiss Stiftung v. Renishaw plc, 20 USPQ2d 1094, 1101).

The amount of detail required to be included in the claims depends on the particular invention and the prior art and is not to be viewed in the abstract, but in conjunction with whether the specification is in compliance with the first paragraph of 35 U.S.C. §112.

In a recent case, the court held:

> [t]he definiteness requirement, however, does not compel absolute clarity. Only claims 'not amenable to construction' or 'insolubly ambiguous' are indefinite. Thus, the definiteness of claim terms depends on whether those terms can be given any reasonable meaning." Slip op. at 7. Datamize, LLC v. Plumtree Software, Inc., __ F.3d ___, __ USPQ2d ____ (Fed. Cir. Aug. 5, 2005) (Clevenger, Bryson, PROST) (N.D. Cal.: Walker) -
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> > In the face of an allegation of indefiniteness, general principles of claim construction apply. Id. at 8.

Applying the Phillips framework, the Fed Cir considered the usage of the term "aesthetically pleasing" in the context of the claims and determined that there is "no objective definition identifying a standard for determining when an interface screen is 'aesthetically pleasing.'" What is "aesthetically pleasing" depends on each person's subjective preference. In contrast, there is an objective standard in cases finding no indefiniteness for terms like "so dimensioned" or "substantially equal." Looking at the specification, the Fed Cir could not find an objective standard for what would be "aesthetically pleasing;" "[s]imply put, the definition of 'aesthetically pleasing' cannot depend on an undefined standard." The Fed Cir then considered the prosecution history and the extrinsic evidence (including expert declarations), but could not find any objective standard for defining the limitation. Finally, the court rejected the patentee's attempt to rely on the meaning of "aesthetically pleasing" derived from design patent law, because the scope and focus of design and utility patents are substantially different.

Analysis

In contradistinction, in this instance, there is an objective standard for defining the term "reactive group;" those of skill in the art understand what a reactive group is. The claims are not ambiguous; the claims reasonably apprise those of skill in the art of the bounds thereof and are as precise as the subject matter permits. As demonstrated below, the term "reactive group" that "effects biopolymer synthesis" is used throughout the literature and is understood by those of skill in the art. For any particular biopolymer, the skilled artisan could select a reactive group that effects the biosynthesis of the biopolymers from appropriate monomers to produce biopolymers selected from among polypeptides, oligonucleotides, peptide nucleic acids and

oligosaccharides. Furthermore, the application is in compliance with 35 U.S.C. §112, first paragraph. To require Applicant to recite particular reactive groups would be unduly limiting and would unfairly limit the scope of the claims.

Understanding by those of skill in the art

Applicant respectfully submits that, as discussed below, the term "any reactive group that effects the biosynthesis of biopolymer synthesis" is readily understood by those of skill in the art. "Reactive groups" are well known and groups that are used in particular synthetic schemes are known as are biopolymers. The term is neither relative nor indefinite and those of skill in the art would readily understand its meaning.

A search of the literature available before the effective filing date evidences this contention. For example, Jenkins *et al.* (*Pure & Applied Chemistry*, Vol 68, No. 12, pp2287-2311, 1996), use the term "reactive group" in the definition of a pre-polymer molecule. Jenkins *et al.* notes on page 2290 that a pre-polymer molecule is "[a] macromolecule (see Definition 1.1) or oligomer molecule (see Definition 1.2) capable of entering, through **reactive groups**, into further polymerization (see Definition 3.1), thereby contributing more than one monomeric unit (see Definition 1.8) to at least one chain of the final macromolecule." (emphasis added) The term "reactive group" thus means a reactive group that is capable of undergoing a chemical reaction, i.e. polymerization, in order to form a part of resulting macromolecule. Thus, the "reactive group" on the pre-polymer molecule, by reacting to form a unit of the final macromolecule, effects the synthesis of the final macromolecule.

In a book review of solid phase peptide synthesis (SPPS), Stewart *et al.* (chapter 1, Solid Phase Peptide Synthesis, 2nd Edition, Pierce Chemical Company, 1984) notes on pages 1-2 that "[t]he basic idea of SPPS is illustrated in Figure 1-1. The insoluble support is a synthetic polymer which bears **reactive groups** (X). The amino acid which will form the C-terminal residue of the peptide to be synthesized is converted to a derivative in which its amino group is protected by a labile protecting group (L). Using appropriate chemistry, this derivative of the C-terminal amino acid is coupled to the reactive polymer."(emphasis added) Those skilled in the art would recognize that without an appropriate reactive group on the insoluble support, the synthesis of peptides would not be possible. Thus, the reactive group on the insoluble support is not any reactive group in general, but rather is a reactive group that is capable of reacting with reactive groups on the first amino acid of the peptide to be synthesized. Therefore, the reactive group on the insoluble support, by reacting with the reactive group on the first amino acid, effects the synthesis of peptides.

Gravert *et al.* (*Chemical Reviews*, Vol. 97, No. 2, 489-509, 1997) provides a review of literature describing organic synthesis on soluble polymer supports. Gravert *et al.* states on page 490 that:

> "[p]olymers employed as soluble supports for liquid-phase synthesis must: (1) be commercially available or rapidly and conveniently prepared, (2) demonstrate good mechanical and chemical stabilities, (3) **provide appropriate functional groups for easy attachment of organic moieties**, and (4) exhibit high solubilizing power in order to dissolve molecular entities with low solubilities and permit the development of a general synthetic methodology independent of the physicochemical properties of target compounds."(emphasis added)

Gravette *et al.* states, for example, on page 490 that the functional groups, *i.e.*, reactive groups, on the polymer supports determine which organic moieties can be attached to the polymer. Gravert *et al.* also states that the functional groups can be derivatized prior to reacting with the organic moieties. For example, Gravert *et al.* states on page 490:

> "The polymeric carrier must withstand the reaction conditions used in solution-phase synthesis, and consequently most soluble supports used in liquid-phase synthesis possess hydrocarbon or alkyl ether backbone structures. By variation of terminal and pendant functional groups of these two backbone structures, polymer properties are determined and may provide sites for attachment of organic moieties. If the conditions of polymerization and choice of monomer allow for suitable polymer functionalization, then anchoring of the initial synthetic structure may be made directly to the support for liquid-phase synthesis; however, often a linking group must be employed to ensure anchor stability throughout synthesis, improve accessibility to reagents, and facilitate cleavage for product recovery."

Therefore, for any given synthetic application, the functional group on the polymer support will be dictated by the functional groups on the organic moieties used. Thus, the reactive groups on the polymer support, by providing the means for attaching organic moieties to the support, effect the synthesis of any given target compounds.

A search of the claims in the Micropatent database, for the words "reactive group" in issued patents yielded more than 1000 different issued US patents that recite this term in the claims. For example, U.S. patent no. 5,132,418, issued to Caruthers *et al.* on July 21, 1992, discloses a process for the preparation of polynucleotides using modified inorganic polymer supports. It is noted in column 1, lines 60-66, that "the modified inorganic polymer supports of the present invention comprise the inorganic polymer to which is chemically bound a nucleoside. The chemical bonding of the nucleoside moiety to the polymer is by means of

reactive groups on the polymer which react with **reactive groups** of the nucleoside molecule." (emphasis added) Claim 4 of the '418 patent recites:

> 4. A process for the production of oligonucleotides which comprises:
>
> (a) treating an inorganic polymer with a coupling agent which agent has a **reactive group** capable of reacting with a **reactive group** carried on a nucleoside; and
>
> (b) combining the treated polymer with a nucleoside or a blocked nucleoside to obtain a nucleoside-modified support or a blocked nucleoside-modified support.(emphasis added)

Therefore, one of skill in the art would understand that the reactive groups on the inorganic polymer support for oligonucleotide synthesis are not any reactive group in general but rather those that are appropriate for reacting with a reactive group on a nucleoside. Thus, the reactive group on the inorganic polymer support, by reacting with a first nucleoside, effects the synthesis of polynucleotides.

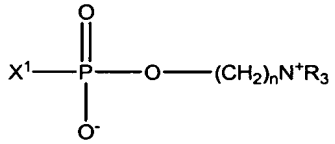
U.S. patent no. 5,554,501, issued to Coassin *et al.* on September 10, 1996, discloses surface activated, organic polymers useful in biopolymer synthesis, such as nucleic acids, peptides and proteins. The '501 patent recites at column 3, lines 38-41:

> "Typically, the C-terminal end of the first amino acid is coupled to a solid support comprising a **reactive group** (i.e., the site of attachment)..."(emphasis added)

One of skill in the art would recognize that the "reactive group" on the solid support disclosed in the '501 patent is not any reactive group in general, but refers to those reactive groups that are capable of forming a bond with a reactive group on the first amino acid used in the synthesis of the biopolymer. Thus, the reactive group on the solid support, by reacting with the first amino acid monomer, effects the synthesis of biopolymers.

U.S. patent no 5,380,904 issued to Chapman *et al.* on January 10, 1995, discloses biocompatible surfaces as well as compounds that are useful in the production of biocompatible surfaces. Claim 1 of the '904 patent recites:

> "1. A method for rendering a surface of a material biocompatible comprising the steps of
> (1) applying to said surface a compound of the formula



> wherein X^1 is a **reactive group** which forms a covalent bond with a **reactive group** on said surface of said material to be rendered biocompatible, each R, which may be the same or may be different, is C_1-C_4 alkyl and n is 2, 3 or 4; and

> (2) reacting said compound and said **reactive group** on said surface under conditions such that the group X^1 forms a covalent linkage with said **reactive group** on said surface thereby rendering said surface biocompatible."(emphasis added)

The '904 patent also states in column 3, lines 18-20, that "[t]he exact chemical nature of the group X^1 will depend upon the chemical nature of the **reactive group** on the surface to be rendered biocompatible." (emphasis added) Therefore, the reactive group on the surface, by reacting with the compound shown in claim 1 of the '904 patent, effects the synthesis of a biocompatible surface.

U.S. patent no. 3,725,111, issued on April 3, 1973, discloses a support medium for the solid phase synthesis of complex molecules such as, for example, polypeptides, polynucleotides, polysaccharides, and proteins. The '111 patent discloses a method of coating glass beads with a low cross-linked polymer. Reactive groups are introduced into the polymer coating, "which will allow ready attachment of the first synthetic component, e.g., the first amino acid by a stable, covalent bond." (see column 2, lines 26-28) Claim 1 of the '111 patent recites:

> "1. A method for the preparation of a glass bead solid support for solid-phase synthesis of complex molecules, said support comprising a glass bead coated with a highly swellable, low cross-linked polymer resin, said resin comprising from about 0.2 to about 20.0 weight percent of the coated glass bead solid support and being characterized as containing **reactive groups**, which method comprises the following steps in combination:
> (a) treating a glass bead with a detergent to purify the surface thereof;
> (b) treating the purified glass bead with an organosilicon compound to promote adhesion of the polymer to the surface thereof;
> (c) polymerizing a mixture of a monomer selected from the group consisting of styrene, phenol-Strioxan, methyl methacrylate, vinyl alcohol, vinyl toluene, vinyl xylene, vinyl naphthalene, vinyl ethyl benzene, c-methyl styrene, vinyl chlorobenzene and vinyl dichlorobenzene or mixtures thereof, and cross-linking agent having a polymerization initiator dispersed therethrough onto the surface of the treated glass bead from step (b) by heating the aforesaid components in the liquid phase;
> (d) treating the polymer coated glass bead from step (c) with a solvent to swell the polymer coating so as to afford a porous polymer matrix which permits rapid diffusion of reagents therein and easy removal of reagents and by-products by filtration and washing;
> (e) treating the swelled polymer-coated glass bead from step (d) with a reagent so as to introduce into said swelled polymer a **reactive group** which is capable of coupling with a free carboxy, amino or hydroxy group of a polyfunctional molecule which is the first component of the complex molecule to be synthesized; and

> (f) washing the reactive group-containing coated bead from step (e) with solvent so as to purify said bead."(emphasis added)

One of skill in the art would recognize that the reactive groups on the support allow for the solid phase synthesis of complex molecules. One of skill in the art would also recognize that the reactive groups on the support are not any reactive group in general, but only those that are capable of reacting with a reactive group on the first synthetic component of the complex molecule to be synthesized. Therefore, one of skill in the art would recognize that the reactive groups on the support disclosed in the '111 patent effect the synthesis of complex molecules.

Such disclosure evidences that those the term reactive group is a term of art recognized by those of skill in the art to have a defined meaning. Further, a particular reactive group selected depends upon the type of biopolymer to be synthesized. Therefore, one of skill in the art would readily understand the term "any reactive group that effects biosynthesis of biopolymers." One of skill in the art would recognize that "any reactive group" must be complementary to the reactive groups on the monomers that are used in the synthesis of biopolymers, which includes polypeptides, oligonucleotides, peptide nucleic acids and oligosaccharides. One of skill in the art would recognize that any reactive group that is present on the LPCs and is capable of reacting with a reactive group on a monomer used in the synthesis of a particular biopolymer, effects the biosynthesis of that biopolymer.

Disclosure in the Specification

The disclosure of the specification further evidences that those of skill in the art would be able to determine the metes and bounds of the instant claims. The specification teaches that X^1 is any reactive group that effects the biosynthesis of biopolymers. X^1 is not any reactive group in general, but only those that are for biopolymer synthesis. The specification states:

> As used herein, a biopolymer is any compound found in nature, or derivatives thereof, made up of monomeric units. Biopolymers include, but are not limited to, oligonucleotides, peptides, peptide nucleic acids (PNAs) and oligosaccharides. Thus, the monomeric units include, but are not limited to, nucleotides, nucleosides, amino acids, PNA monomers, monosaccharides, and derivatives thereof.

Thus, X^1 is a reactive group that effects synthesis of biopolymers, which include polypeptides, oligonucleotides, oligosaccharides and peptide nucleic acids (PNA). As amended, the claims recite the particular biopolymers synthesized, thereby defining the reactive groups. As established above, particular reactive groups for synthesis of particular biopolymers are known to those of skill in the art.

For example, at page 21, the specification states:

> X1 is any reactive group which can be used in biopolymer synthesis (see, e.g., U.S. Patent No. 5,198,540, the disclosure of which is incorporated herein by reference), and is preferably OH, SH, NH_2, COR^5 or $COOR^4$

Hence the specification describes examples of reactive groups.

The specification exemplifies methods of synthesis of biopolymers using the X^1 reactive groups on the LPCs. For example, page 7, line 28 through page 8, line 6, recites:

> "In one embodiment, the methods involve the steps of (a) reacting an LPC of formula $Sp(X^1)_n$, provided herein, with a first monomer N^1; (b) separating and purifying the product of step (a) to afford a compound of formula $Sp(X^1\text{-}N^1)_n$; (c) reacting the product of step (b) with a second monomer N^2, a dimer $N^2\text{-}N^3$ or a trimer $N^2\text{-}N^3\text{-}N^4$; and (d) repeating steps (b) and (c) using the desired monomers, dimers or trimers to produce the desired LPC-bound biopolymer of formula $Sp(X^1\text{-}N^1\text{-}N^2\text{-}\ldots\text{-}N^m)_n$, where m is 3 to 100, preferably 3-50, more preferably 3-25, most preferably 3-10. In another embodiment, the methods further involve the step of (e) cleaving the biopolymer from the LPC."

The specification teaches that monomers (i.e., N) used in preparing the biopolymer will depend on the biopolymer desired. For example, monomers that are used in the methods include nucleotides, nucleosides, natural and unnatural amino acids, PNA monomers and monosaccharides.(see, e.g. page 8, lines 25-28) As discussed above, it is understood by those of skill in the art that the reactive groups that are present on the monomers that are used in the biosynthesis of the biopolymers dictate which reactive groups are desired on the LPCs, i.e. X^1.

The specification teaches that X^1 does not encompass any reactive group, but only those groups that are useful in biopolymer synthesis. The specification provides non-limiting examples of such reactive groups, including, but not limited to, halide, OH, SH, NH_2, COR^5 and $COOR^4$, where R^4 is hydrogen, alkyl, aryl, aralkyl, heteroaryl, heteroaralkyl, heterocyclyl or heterocyclylalkyl, and R^5 is halide, heteroaryl, aryl or pseudohalide. (see, *e.g.,* page 26, lines 19-21, page 31, lines 10-15).

The specification also recites on page 17, line 25 through page 18, line 29:

> "In another preferred embodiment, carrier molecules of the general formula $Sp(OH)_n$, and the corresponding thio and amino derivatives, are used directly in the provided methods if they are to react with reactive carboxyl groups. However, they are usually employed in the form of activated compounds, which can be obtained, for example, in the following manner:
>
> a) by reaction with dicarboxylic acid anhydrides, for example succinic or adipic anhydride, according to the equation
> $\text{-Sp-OH} + (\text{OC-R-CO})_2\text{O} \rightarrow \text{-Sp-O-CO-R-COOH}$;
>
> or
>
> b) by reaction with trityl derivatives according to the equation
> $\text{-Sp-OH} + \text{HOOC-C}_6\text{H}_4(\text{C}_6\text{H}_5)_2\text{COH} \rightarrow$

-Sp-O-CO-$C_6H_4(C_6H_5)_2$C-OH → -Sp-O-CO- $C_6H_4(C_6H_5)_2$C—Cl;

this reaction can be carried out in the presence of a condensing agent or after conversion of the acid function into an acid chloride function; or

c) by reaction with dichlorosiloxanes according to the general equation

-OH + $Z(Me)_2Si$-A-$Si(Me)_2Z$ → -O-$Si(Me)_2$-A-$Si(Me)_2Z$,

wherein A is alkylene, arylene, -O- or a combination of these groups and Z is halogen; or

d) by reaction with hydroxyl substituted trityl derivatives, to form trityl ether derivatives, for example of the general formula

-Sp-O-$C_6H_4(C_6H_5)_2$C-OH → -Sp-O-$C_6H_4(C_6H_5)_2$C-Cl ;

or

e) by reaction with, for example, acrylonitrile, followed by alcoholysis of the nitrile and reaction of the resulting ester with an α,ω-diamine, to form amino derivatives, for example of the general formula

-Sp-O-$(CH_2)_2$-C(O)-NH-$(CH_2)_x$-NH_2

wherein x is 0-6. The amine is then further derivatized according to any of a) through d), above, prior to biopolymer synthesis.

If the corresponding thio or amino derivatives are used, the corresponding S or N compounds are formed."

The specification provides examples of the X^1 groups that are used for synthesis of various biopolymers, thereby further defining the scope of X^1. LPCs for use in oligonucleotide synthesis can contain, for example, a carboxylic acid group at the terminus of X^1 (see, e.g., page 32, lines 30-31). This type of functionality may be used to form an ester linkage to, for example, the 3′-OH group of a first nucleotide or nucleoside monomer. The specification provides detailed description on modifications of LPCs for use in oligonucleotide synthesis when X^1 is OH, SH, NH_2, $COOR^4$ and COR^5 (see, e.g. page 32, line 34 through page 34, line 11).

As noted above, the specification also recites at page 17, lines 10-24:

"Examples of the reactive group X^1 which are customary in nucleotide chemistry are described in Liebigs Ann. Chem. 1978, 839-853 and in Nucleic Acids Research, Symposium Series No. 7, 1980, 39-59. Typical examples are, inter alia, the following:

1. Acid halides, in particular acid chlorides and acid bromides;
2. Carboxylic acid groups, which can react with 5'-OH groups, for example in the presence of condensing agents; they can also be converted into activated trityl chloride derivatives according to the following equation:

-CCOOH + Y-$C_6H_4(C_6H_5)_2$C-Cl → -CO-Y'-$C_6H_4(C_6H_5)_2$C-Cl,

wherein Y = OH, SH or NH_2; and Y' = O, S or NH;

3. Activated ester functions of the general formula -COOR'; and
4. OH, SH and NH_2 groups."

Thus, LPCs for use in peptide synthesis or peptide nucleic acid synthesis can contain, for example, a haloalkyl, hydroxyl, thio or carboxyl group at the terminus of X^1. The hydroxyl or thio groups may be used to form ester or thioester linkages to the carboxyl group of a first amino acid monomer or PNA monomer. Preferred haloalkyl groups are benzylic halides that can form benzylic esters with the carboxyl terminus of a first monomer. The carboxyl group of X^1 may be used to form an amide linkage to the amino group of a first amino acid or PNA monomer (see, e.g. page 34, lines 13-20 and page 35, lines 15-22). The specification provides detailed description on modifications of LPCs for use in peptide synthesis when X^1 is OH, SH, NH_2, $COOR^4$ and COR^5 (see, e.g. page 34, line 22 through page 35, line 13).

LPCs for use in oligosaccharide synthesis can contain, for example, a hydroxyl, thio or carboxyl group at the terminus of X^1. The hydroxyl or thio groups may be used to form glycosyl linkages to the first saccharide monomer. The carboxyl group may be used to form an ester linkage to a hydroxyl (e.g., the 5- or 6-hydroxyl) group of a first saccharide monomer (see, e.g., page 35, lines 24-29).

Therefore, the metes and bounds of the variable X^1, when viewed in light of the specification and the knowledge and understanding of one of skill in the art and as employed in the claims is defined and not relative and is understood by those of skill in the art.

The application is in compliance with 35 U.S.C. §112, first paragraph.

The application has been deemed to be in compliance with 35 U.S.C. §112, first paragraph. Previous responses discussing and obviating this issue are incorporated by reference. In rejecting the term "reactive group" as indefinite, however, the Office is setting forth a 35 U.S.C. §112, first paragraph rejection in the guise of a 35 U.S.C. §112, second paragraph rejection. Any rejections under 35 U.S.C. §112, first paragraph have been vetted and obviated during this lengthy prosecution.

It is clear that the specification in light of the knowledge of those of skill in the art teaches those of skill in the art how to make and use what is claimed. As established in response of record and above, the skilled artisan would be able to identify reactive groups to employ for synthesis of a particular biopolymer. To limit the claims to only recited groups would be unfair, unduly limiting and contrary to the public policy upon which the patent laws are based. The Examiner is reminded that applicant is entitled to claims that are commensurate in scope not only with what applicant has specifically exemplified, but commensurate in scope with that which one of skill in the art could obtain by virtue of that which the applicant has disclosed. It would be unfair and unduly limiting to require applicant

to limit the claims to exemplified species when the specification clearly places those of skill in the art in possession of a larger genus of the LPCs as instantly claimed. Therefore, it would be unfair, unduly limiting and contrary to the public policy upon which the U.S. patent laws are based to require applicant to limit the claims only to the exemplified species. See, e.g., In re Goffe, 542 F.2d 801, 166 USPQ 85 (CCPA 1970):

> for the Board to limit appellant to claims involving the specific materials disclosed in the examples so that a competitor seeking to avoid infringing the claims can merely follow the disclosure and make routine substitutions "is contrary to the purpose for which the patent system exists - to promote progress in the useful arts".

The public purpose on which the patent law rests requires the granting of claims commensurate in scope with the invention disclosed. This requires as much the granting of broad claims on broad inventions as it does the granting of more specific claims on more specific inventions" In re Sus and Schafer, 49 CCPA 1301, 306 F.2d 494, 134 USPQ 301, at 304.

In this instance, to require applicant to limit the claims to only the exemplified species would permit those of skill in the art to practice what is disclosed in the application, but avoid such limited claims. One of skill in the art could readily select different reactive groups to produce LPCs for biopolymer synthesis based upon the disclosure of the application, but avoid infringing claims that recite specific groups. The first paragraph of §112 requires only that the disclosure be sufficient to teach one of skill in the art how to make and use the claimed subject matter without undue experimentation. The specification has done so. One of skill in the art based upon the specification and his or her knowledge could select reactive groups for synthesis of particular biopolymers. The Patent Office has provided no evidence to the contrary. Enablement is a legal determination that assesses whether a specification teaches one of skill in the art to make and use what is claimed. As noted enablement is not precluded even if some experimentation is necessary, as long as the amount of experimentation is not undue. Atlas Powder Co. v. E. I. Du Pont De Nemours Co., 750 224 USPQ 409, 3 (Fed. Cir. 1984); W. L. Gore and Associates v. Inc., 721 220 USPQ 303, 315 (Fed. Cir. 1983).

Nothing more than objective enablement is required, and therefore it is irrelevant whether this teaching is provided through broad terminology or illustrative examples. In re Marzocchi, 439 220, 223, 169 USPQ 367, 369 (CCPA 1971). An analysis of whether the rejected claims are supported by an enabling disclosure requires a determination of whether that disclosure contained sufficient information regarding the subject matter of the claims as to teach one of skill in the art how to make and use what is claimed. Factors to be considered by the examiner in determining whether disclosure would require undue experimentation have

been summarized in In re Wands, 858 731, 737, 8 1400, 1404, (Fed. Cir. 1988) and are outlined in the Guidelines. These factors include: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the claimed subject matter, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. All factors must be considered. A deficiency in meeting one factor does not preclude a finding of enablement.

To establish a prima facie case of lack of enablement, the Examiner has the initial burden to establish a reasonable basis to question the enablement provided for what is claimed. In re Wright, 999 1557, 1561-62, 27 1510, 1513 (Fed. Cir. 1993). (examiner must provide a reasonable explanation as to why the scope of protection provided by a claim is not adequately enabled by the disclosure). See also Morehouse, 545 162, 192 USPQ 29 (CCPA 1976). The threshold step in resolving this issue is to determine whether the Examiner has met this burden of proof by advancing acceptable reasoning inconsistent with enablement.

In the instant case, the Examiner has not provided any reasons why one of skill in the art could not make or use the claimed LPCs commensurate in scope with the claims (112, first paragraph) and has not set forth any reasons who one of skill in the art could not identify reactive groups for biopolymer synthesis. Therefore, the Examiner has not met his burden.

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In view of the above, reconsideration and allowance of the application are respectfully requested.

Respectfully submitted,

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